

# Exhibit 8

**File Name:**

**ANAVEX LIFE SCIENCES CORP.**

**Q1 2023 Earnings Call**

February 7, 2023

**LEGEND:**

[UI]: Unintelligible

[PH]: Phonetic

**CORPORATE PARTICIPANTS**

**Clint Tomlinson**

Vice President -Operations Anavex Life Sciences Corp.

**Christopher U. Missling**

President, Chief Executive Officer & Director Anavex Life Sciences Corp.

**Sandra Boenisch**

Principal Financial Officer & Treasurer Anavex Life Sciences Corp.

**OTHER PARTICIPANTS**

**Soumit Roy**

Analyst

JonesTrading Institutional Services LLC

**Yun Zhong**

Analyst

BTIG LLC

**MANAGEMENT DISCUSSION SECTION**

**Clint Tomlinson**

Good morning everyone, and welcome to the Anavex Life Sciences Fiscal 2023 First Quarter Conference Call. My name is Clint Tomlinson, and I will be your host for today's call. At this time, all participants are in a listen-only mode. Later, we will conduct a question-and-answer session. During this session, if you'd like to ask a question, use the Q&A box or please raise your hand. Note that this conference is being recorded. The call will be available for replay on Anavex's website at [www.anavex.com](http://www.anavex.com).

With us today is Dr. Christopher Missling, President and Chief Executive Officer; and Sandra Boenisch, Principal Financial Officer. Before we begin, please note that during this conference call, the company will make some projections and forward-looking statements. These statements are only predictions based on current information and expectations and

involve a number of risks and uncertainties. We encourage you to review the company's filings with the SEC. This includes, without limitation, the company's Forms 10-K and 10-Q, which identify the specific factors that may cause actual results or events to differ materially from those described in these forward-looking statements.

These factors may include, without limitation, the risks inherent in the development and/or commercialization of potential products, uncertainty in the results of clinical trials or regulatory approvals, need and ability to obtain future capital, and maintenance of intellectual property rights. And with that, I would like to turn the call over to Dr. Missling.

**Christopher U. Missling**

Thank you, Clint. We appreciate everyone joining us on today's conference call to review our most recently reported financial results and to provide a business update. We are excited with the continued advancement of our lead product candidate, ANAVEX 2-73, in Alzheimer's disease and Rett syndrome, as we maintain our attention on execution across each of our clinical programs and overall business operations.

We were very pleased to present top-line data of the randomized, double-blind, placebo-controlled Phase 2b/3 study for the treatment of early Alzheimer's disease at the CTAD Congress 2022 on December 1.

The trial met both core primary and secondary endpoints, showing statistically significant reduction of clinical decline as measured by those endpoints. We are excited about the data and plan to submit the data for publication in a peer-reviewed medical journal in the near term. As a reminder, Alzheimer's disease represents a growing burden to healthcare systems and societies worldwide. This disease is often multifactorial and complex in nature. We believe that our precision medicine platform, the novel central nervous system mechanism, improved the chance of clinical success.

We are pleased by the results of the placebo-controlled Phase 2b/3 study Alzheimer's disease trial, which data suggests that ANAVEX 2-73, blarcamesine, an orally-available small molecule activator of the upstream SIGMAR1 receptor, is pivotal to restoring neural cell homeostasis and promoting new plasticity, and might be at the forefront of biomarker-guided, pathway-based, targeted precision medicine drug development.

We look forward to presenting the complete dataset of the study as well as the other long-term study data of the other programs, including Parkinson's disease, dementia and Rett syndrome. With a deep portfolio of promising therapies, we believe that Anavex remains well-positioned to address the urgent needs of patients affected by neurodegenerative and rare neurodevelopmental diseases.

Going back to the Rett Syndrome program, we announced recently on February 2nd last week the completion of enrollment of the randomized placebo-controlled EXCELLENCE Phase 2/3 study for the treatment of pediatric patients with Rett syndrome. We expect to announce top-line results from the study in the second half of this year.

In Parkinson's disease dementia, we are planning to announce data from the 48-week open label extension of the previously successfully completed Phase 2 study. In other indications, recent communication with the FDA confirms our strategy to advance ANAVEX 2-73 for the treatment of Fragile X syndrome. We plan to initiate this trial soon, and we'll share more details about this clinical program in the near term, as it becomes available. Further, pipeline expansion of the Anavex platform using gene biomarkers of response, applying precision medicine to neurological disorders is expected, including planned initiation of an ANAVEX 2-73 imaging-focused Parkinson's disease clinical study, sponsored by the Michael J. Fox Foundation, the planned initiation of a Phase 2/3 clinical trial for the treatment of a new rare disease indication, and the planned initiation of an ANAVEX 3-71 Phase 2 clinical trial for schizophrenia.

And last but not least, we expect several clinical publications involving ANAVEX 2-73 and ANAVEX 3-71 and a Rett syndrome Burden of Illness study.

And now I would like to direct the call to Sandra Boenisch, Principal Financial Officer of Anavex, for a brief financial summary of the recently reported quarter.

**Sandra Boenisch**

Thank you, Christopher, and good morning to everyone. We continue to demonstrate operating fiscally responsibly. During our first fiscal quarter, general and administrative expenses were \$3.3 million, compared to \$3.1 million for the comparable quarter of fiscal 2022. Our research and development expenses for the quarter were \$12.1 million, as compared to \$8.7 million for the comparable quarter of fiscal 2022. Overall, we reported a net loss of \$13 million or \$0.17 per share, inclusive of \$5.3 million in non-cash compensation items.

Our cash position at December 31, 2022, was \$103.6 million. During the quarter, we utilized cash and cash equivalents of \$5.8 million to fund our operations. At our current cash utilization rate, we believe we have sufficient cash runway to fund operations and clinical programs beyond the next four years, consistent with guidance in previous quarters.

The increase in research and development expenses over the comparable period is primarily related to the expansion of our team and an associated increase in compensation and non-cash charges period over period, as well as costs associated with our Phase 2b/3 study, Anavex 2-73-AD-004, and the manufacture of additional clinical trial supply for upcoming pipeline programs. Thank you, and now back to you, Christopher.

**Christopher U. Missling**

Thank you, Sandra. This is an exciting time for the company, and we remain on track for completion and readout of ongoing clinical trials and initiation of additional biomarker-driven precision medicine clinical trials as planned.

I would like now to turn the call back to Clint for Q&A.

**Q&A**

**Clint Tomlinson**

Thank you, Christopher. We will now begin the Q&A session. If you have a question, raise your hand or please put it in the Q&A box. The first question is going to come from Soumit Roy at Jones Research. I think you can go ahead, Soumit.

**Soumit Roy                    Q**

Hi, everyone. Congratulations on the progress. Could you give us a little color on what kind of details on the Alzheimer's data we are going to expect? Are we going to see some MRI data, or time course of how the reduction in the cognitive decline has occurred, or something like that?

**Christopher U. Missling        A**

Yeah, so several items will be in the paper, in the publication. Of course, we made sure that the study has a lot of biomarkers and additional measures of endpoints. So among them is MRI, which is a very important marker of pathology, which is the most accurate – it's a picture of the brain and it's very well-described that the brain atrophy moves in this pathology aggressively. So that will be part of the analysis, as well as additional biomarkers of pathology like A-beta and tau, as well as the biomarker which is specific to ANAVEX, which is the SIGMAR1 variant analysis, which was clearly pre-specified, which you remember we noted that patients with a wild-type SIGMAR1 receptor did much better compared to those who had the variant. But because the variant carriers were in the minority, often that signal overall was not affecting the significance of all patients, but it was notable that there was a better outcome in patients with the wild-type SIGMAR1 carrier status in previous studies. So we are looking forward to seeing how this plays out in this study as well.

But then, also, we will see the response to the endpoints of the study depending on doses, as well as over the period of time, because we measure every three months the time points of this area within this study. And then we will see additional endpoints, which have been included in this study, like quality of life, sleep quality, and other behavioral measures which are related to the Alzheimer's pathology.

**Soumit Roy                    Q**

Thank you for the detail. That was really helpful. Should we expect the data to come out first half of this year, or are you going to be more like second half should be our expectation?

**Christopher U. Missling        A**

We actually try to do this as soon as possible because we want to share that also with the agencies, the FDA and Europe. So we are really keen to do that as soon as possible. But at this point in time, it's too premature to give guidance on the timing, but you can be assured we'll do that as soon as possible.

**Soumit Roy**

Great, thank you so much for taking the questions and congrats on all the progress.

**Christopher U. Missling**

Thank you.

**Clint Tomlinson**

The next call comes from Yun Zhong at BTIG. I think you can go ahead, Zhong.

**Yun Zhong Q**

Hi. Good morning. Thank you very much for taking questions. So, Christopher, can you talk about your plan for the regulatory discussion with the FDA on the Alzheimer's indication? Have you started any [Technical Difficulty] talk to the FDA?

**Christopher U. Missling**

Sorry, a bit of cut off.

**Clint Tomlinson**

I'm sorry, can you ask that again? We had a – we had a glitch.

**Yun Zhong Q**

Okay, no problem. So yeah, I was wondering your plan for the discussion with the FDA. Have you started anything, or do you have to wait for additional data to be available before you can start that conversation with the FDA?

**Christopher U. Missling A**

That's correct. The FDA engages when you have data, and that's exactly where we are. So the data means a complete data set as far as possible. And that's what we want to – that's why we are so keen to complete that, as I just mentioned, because that's how you can engage with the FDA as well as with the European EMA agency.

**Yun Zhong Q**

Okay. And then switching to the Rett syndrome study, I believe the press release announcing over enrollment had the language that with the FDA's input, you are using the primary endpoint. So I wanted to confirm that the primary endpoint is RSBQ AUC, similar to or the same to the one used in the AVATAR study. And so has the FDA agreed that the AUC, the modified RSBQ scale can be an appropriate endpoint for Rett syndrome study?

**Christopher U. Missling A**

We have it described in clinicaltrials.gov, and it was also never changed in clinicaltrials.gov for the EXCELLENCE study. It is - the RSBQ is primary endpoint and the CGI-I is key secondary endpoint. This is over the course of the trial.

**Yun Zhong Q**

Is that the same endpoint that was used in the AVATAR study?

**Christopher U. Missling A**

It's slightly different. So it's actually the measurement over time from beginning to end of trial.

**Yun Zhong Q**  
Not AUC?

**Christopher U. Missling A**  
Not AUC.

**Yun Zhong Q**  
Not AUC.

**Christopher U. Missling A**  
Exactly, yes. Because the study is large enough that it can carry the signal by itself without AUC.

**Yun Zhong Q**  
Okay, great. So the last question, I believe the original plan is to initiate all those studies that you talked about by year-end last year. And I understand that the focus was on the Alzheimer's disease program. But are there any specific reasons for the delay, or also are you able to provide any specifics in terms of timing? When do you expect to initiate those studies?

**Christopher U. Missling A**  
Yes, we were very ambitious last year when we made those plans. And the attention to detail required really to finance and work on the specific protocol. Because it's easy to start any trial. It's more difficult to finish a trial successfully, and that's what we're aiming for. So I think we should appreciate that initiating a trial is not difficult. It's about making the trial successful and meaningful for – for when it's going. And so when you look at each trial, there's always things to consider, and you learn to improve it as you go before you really start it. And we didn't want to rush it. So that's why we want to say we want to do this with the right timing. But obviously, we will catch up very nicely now with all these trials which we planned to do, and they are still on track to be executed.

**Yun Zhong**  
Okay, great. Thank you very much.

**Christopher U. Missling**  
You're welcome.

**Clint Tomlinson**  
I don't see any further questions at this time. Christopher?

**Christopher U. Missling**  
Good. Thank you. Again, we are very much looking forward and we're very excited about the company's potential as we build on biomarker-driven precision medicine studies with significant unmet medical need and economic burden. And we're looking forward to upcoming data readouts in Parkinson's dementia and Alzheimer's disease with complete

data set, as well as Parkinson's dementia open label extension and the pediatric Rett syndrome study. Thank you very much.

**Clint Tomlinson**

All right. Thank you, ladies and gentlemen. This concludes today's conference. We appreciate you participating and you may now disconnect.